

REMARKS

Status of the Claims.

Claims 33-38, and 80-82 are pending with entry of this amendment, claims 1-32, and 39-79 cancelled and claims 80-82 being added herein. Claims 33, 35, and 37 are amended herein. These amendments introduce no new matter. Support is replete throughout the specification (*e.g.*, page 11, last paragraph, in the claims as originally filed, *etc.*).

Election/Restriction.

The Examiner improperly withdrew claims 1-34 and 39-79 from consideration as allegedly being drawn to a non-elected invention. Applicants note, however, that **pursuant to the restriction requirement, Group III, claims 33-38, drawn to a DNA encoding a bilin reductase and to a cell comprising the DNA, was previously elected.** No restriction or election of species between claims 33-34 and 35-38 has ever been presented by the examiner. Accordingly, the Examiner's withdrawal of claims 33 and 34 from consideration at this time is improper and Applicants regard claims 33-38 as pending and presently under consideration.

Pursuant to a restriction requirement made final, Applicants cancel claims 1-32, and 39-79 with entry of this amendment. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

Applicants further note that the Examiner characterized Applicants traversal of the restriction as allegedly being on the ground(s) that the various bilin reductases in claims 1-19 are species and are not patentably distinct invention. **For the record, Applicants never asserted that the individual bilin reductases are not patentably distinct inventions.** This is not presently, and never has been the definition of a species.

Rather Applicants argued that it was possible to examine the generic claim with respect to an initial species election without undue experimentation. Moreover, it is also Applicants contention that, in accordance with prevailing case law (*see, e.g., In Re Weber, Soder and Boksay* 198 USPQ 328, 331-332 (CCPA 1978), *In Re Haas* 179 USPQ 623, 624, 625, and *In Re Haas* 198 USPQ 334-337) Applicants are entitled to have their generic claim examined fairly on the merits. It will be noted that the generic claim refers to a bilin reductase comprising an amino acid **consensus sequence**

as illustrated in Figure 5 or in Figure 10 and having bilin reductase activity. It is not undue burden to examine the claim with respect to the consensus sequence as recited and in view of this, the Examiner's restriction to a particular bilin reductase recited in a later claim is improper and can only properly be regarded as an election of species.

Information Disclosure Statement.

Applicants note with appreciation the Examiner's thorough consideration of the references cited in the Information Disclosure Statement (Form 1449) submitted on _____.

Claim objections.

Claim 35 was objected to as being dependent upon a non-elected base claim. Claim 35 is amended herein to independent form thereby obviating this objection.

Objection to the specification.

The specification was objected to because the brief description of the drawings refers to Figure 3A, but there allegedly was no corresponding Figure 3A in the drawings. The formal drawings provided herein are properly labeled and identify a Figure 3A thereby obviating this objection.

Drawings.

The drawings were objected to because Figure 3B was allegedly not preceded by a Figure 3A. The replacement figures provided herewith correct the labeling so that Figure 3A is clearly so labeled thereby obviating this objection.

35 U.S.C. §101.

Claims 35-36 were rejected under 35 U.S.C. §101 as allegedly directed to a non-statutory subject matter because claims 35-36 allegedly "read on a product of a human cell".

First Applicants note that the claims, as amended herein, **do not** read on the product of a human cell, and more importantly, do not read on a naturally occurring product.. For example, independent claims 33 and 35 read on an **isolated** nucleic acid that encodes a bilin reductase, while independent claim 35 is directed to a cell comprising **a heterologous** nucleic acid that encodes a bilin reductase. Isolated nucleic acids and cells comprising a heterologous nucleic acid are not naturally occurring products. Consequently, the pending claims are not drawn to non-statutory subject matter and the rejection under 35 U.S.C. §101 should be withdrawn.

Applicants also note, for the record, that whether or not the claims read on the product of a human cell is not the standard for rejection under 35 U.S.C. §101. It is well accepted that human cells can be engineered to express heterologous products and that such cells are statutory subject matter under §101.

35 U.S.C. §112, First Paragraph.

Claims 35-38 were rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabling for a nucleic acid molecule encoding a HY2 bilin reductase not homologous to SEQ ID NO:33. Applicants traverse.

The pending claims **are not** directed to all bilin reductase. To the contrary, the claims pertain to bilin reductases "**comprising an amino acid consensus sequence as illustrated in Figure 5 or in Figure 10 and having bilin reductase activity.**" In effect, the claims provided for bilin reductase that are orthologues of HY2.

The Examiner is reminded that enablement is not precluded by the necessity of some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. "[T]he key word is 'undue' not 'experimentation'. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Whether undue experimentation is required by one skilled in the art is typically determined by reference to eight factors considered relevant to the inquiry: (1) quantity of experimentation necessary; (2) amount of guidance presented; (3) presence of working examples; (4) nature of the invention; (5) state of the prior art; (6) relative skill of those in the art; (7) predictability of the art; and (8) breadth of the claims. *In re Wands, supra*. Moreover, the Federal Circuit Court of Appeals has determined that routine screening (*e.g.* screening antibodies for particular binding specificity) **does not** constitute undue experimentation.

In the instant case, the only experimentation that might be involved in validating other putative bilin reductases is screening proteins comprising the recited consensus sequence for bilin reductase activity. Thus the experimentation is at most, routine (Wands Factor 1). Identification and screening for such bilin reductases is easily and routinely performed by one of skill in the art and considerable guidance for such methods is provided by the presence of working examples (Wands Factors 2 and 3). The nature of the invention is quite straightforward, pertaining to a clearly defined

class of molecules having a characteristic activity (Wands Factor 4). The prior art is well developed with respect to the identification of such molecules given the information provided in the specification (Wands Factor 5). The relative skill in the art is high, typically Ph.D. (Wands Factor 6). In view of the recited consensus sequence and required activity, the breadth of the claims is relatively narrow (Wands Factor 8).

Thus, when analyzed in light of *In re Wands*, practice of the pending claims does not require undue experimentation and the rejection of these claims under 35 U.S.C. §112, first paragraph, should be withdrawn.

35 U.S.C. §112, second paragraph.

Claims 35 and 37-38 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because of the phrase "conservative substitutions" which occurred in claim 19. The phrase "conservative substitutions" has been eliminated with entry of this amendment thereby obviating this rejection.

Claims 37-38 were rejected under 35 U.S.C. §112, second paragraph, because the recitation of stringent hybridization conditions was allegedly unclear. Claims 37-38 are amended herein to recite particular hybridization conditions thereby obviating this rejection.

Claims 37-38 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite in the recitation of "hvrccr" or "atrcr". Reference to these terms is eliminated with entry of this amendment thereby obviating this rejection.

Claim 38 was alleged indefinite in the recitation of the phrase "wherein said nucleic acid is a vector" because according to the Examiner, nucleic acids are not normally hybridized with vectors. Applicants traverse. Applicants traverse. That a nucleic acid may or may not be normally hybridized with a vector is immaterial to the definiteness of the claims. The hybridization language is used to characterize the nucleic acid encoding the bilin reductase as recited in the parent claim. This sequence can readily be hybridized and it can be placed in a vector. Indeed, the hybridization can readily be performed with a vector comprising the nucleic acid encoding the bilin reductase. The claims when "... read in light of the specification [it] reasonably apprise[s] those skilled in the art both of the utilization and scope of the invention", and the language is as precise as the subject matter permits." (*see, e.g., Hybritech Inc. v Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986) *cert.*

denied 480 U.S. 947 (1987) *citing Shatterproof Glass*, 225 USPQ 634, 641 (Fed. Cir. 1985). Accordingly, claim 38 is not indefinite and the rejection on these grounds should be withdrawn.

35 U.S.C. §102(a).

Claim 35 and 37 were rejected under 35 U.S.C. §102(a) as allegedly anticipated by Lin *et al.* as identified in the sequence search provided with the Office Action.). Applicants traverse.

A careful reading of the Sequence Search provided by the Examiner shows that Lin *et al.* **did not** identify the sequence of SEQ ID NO:33. Lin *et al.* deposited the *Arabidopsis thaliana* chromosome III BAC F3L24 **genomic sequence**. This is a 106,688 bp nucleic acid sequence in which no genes were identified (*see, e.g.*, GenBank Listing AC011436). Consequently the Lin *et al.* deposit does not provided the claimed isolated nucleic acid encoding a bilin reductase.

The particular sequence identified by the Examiner as allegedly 100% identical with SEQ ID NO:33 of the instant invention was published by Kochi et al. (2001) Plant Cell 13: 425-436, a copy of which is enclosed as Exhibit A. This publication is the inventor's own work.

If the Examiner wishes to maintain the rejection in light of the Koichi *et al.* paper, Applicants will provide a Katz declaration upon an indication of otherwise allowable subject matter thereby obviating this rejection.

35 U.S.C. §103(a).

Claims 35-38 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of Lin *et al.* in view of Hollis *et al.* (U.S. Patent 5,538,885). According to the Examiner Lin *et al.* does not teach a vector or host cell comprising the recited DNA. The Examiner then relied on Hollis *et al.* as teaching expression systems.

As noted above, Lin *et al.* discloses a 106,688 bp BAC comprising chromosome 3 of *A. thaliana*, and **does not** disclose the sequence of SEQ ID NO:33. This sequence was provided by Kochi *et al.* (2001) *Plant Cell* 13: 425-436. Upon an indication of otherwise allowable subject matter, Applicants will provide as Katz declaration eliminating Koichi *et al.* as an available reference and thereby obviating the rejection under 35 U.S.C. §103(a).

Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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Respectfully submitted,



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